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Docket No.: 01780/000F908-US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Michael Delk et al.

Application No.: 09/481,120

Confirmation No.: 5209

Filed: January 11, 2000

Art Unit: 3763

For: ELECTRICALLY POWERED SURGICAL
IRRIGATOR

Examiner: Kevin C. Sirmons

APPELLANT'S BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This brief is submitted under 37 CFR §1.192 on behalf of Appellants in the above-identified case. A Notice of Appeal was filed on February 6, 2004. This brief is submitted in triplicate, accompanied by the fee set forth in 37 CFR §1.17(f). The Commissioner is hereby authorized to charge any additional fees up to \$500 or credit any overpayment to Deposit Account #04-0100.

This brief contains items under the following headings as required by 37 C.F.R. §1.192 and M.P.E.P. §1206:

- I. Real Party In Interest
- II. Related Appeals and Interferences
- III. Status of Claims
- IV. Status of Amendments
- V. Summary of Invention
- VI. Issues
- VII. Grouping of Claims
- VIII. Arguments
- IX. Conclusion
- Appendix A Claims

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I. REAL PARTY IN INTEREST

The assignee, C.R. Bard, Inc., is the real party in interest.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 12-16 are pending in this application. Claims 12-16 were rejected under 35 U.S.C. §103(a) and are the subject of this appeal.

A copy of claims 12-16 is provided in the Appendix immediately following this brief.

IV. STATUS OF AMENDMENTS

No amendment was filed after the final rejection.

V. SUMMARY OF INVENTION

The invention relates to a battery powered surgical irrigator of the type described in Saravia et al. U.S. Patent No. 5,484,402 and Delk et al. U.S. Patent No. 5,807,313 (Specification, pp 1,2). Such irrigators include a pumping unit which includes a pump and the batteries required to power the pump. In addition, tubing and wiring extend from the pumping unit to the handpiece used by the surgeon to irrigate a surgical site. The pumping unit contains an integral spike so that the pumping unit can be spiked directly into the irrigation bag without the need for tubing between the irrigation bag and pumping unit. In order to simplify the set-up process, the spike is typically enlarged or provided with a rib or the like in order to support the weight of the pumping unit. Otherwise, the friction between the spike and irrigation bag fitting would be insufficient to support the weight of the pumping unit.

The present invention is shown in Figure 1 in which pumping unit 10 receives liquid from a supply bag 12 that can be forced under pressure through outlet tubing 26 to a handpiece 14.

The invention differs from the Saravia et al. and Delk et al. patents by providing a short flexible tube 13 which connects the inlet of pumping unit 10 to the irrigation bag 12. A spike 18 at the opposite end of tube 13 is provided with a lubricant such as silicone. The lubricant makes it relatively easy to insert the spike into the irrigation bag fitting, but it also makes it impossible for the spike to be used to support the pumping unit. Consequently, the invention requires that separate clips 16 (Fig. 2) integrally formed with the pumping unit be provided for attachment to the IV pole 19 on which the irrigation bag is supported.

VI. ISSUES

Are claims 12-16 unpatentable under 35 U.S.C. §103(a) over Kullas (U.S. Patent No. 6,436,072) in view of Dennehey et al. (U.S. Patent No. 4,201,406)?

VII. GROUPING OF CLAIMS

Claims 12-16 are grouped together.

VIII. ARGUMENTS

a. The Examiner's Rejection (Section 103)

In the Final Rejection dated October 6, 2003, the Examiner rejected claims 12-16.¹ The references are described below.

Kullas shows the basic combination of a pumping unit, hand piece, and tubing connecting the output of the pumping unit to the hand piece. Kullas also discloses a spike for connecting the pumping unit to an irrigation bag. The Examiner recognized that Kullas "does not disclose a lubricant (silicone) coating on the spike", but because "Dennehey discloses a lubricating material that may be applied to the spike", the Examiner concluded that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the spike of

¹ The detailed action only refers to claims 12-14 (page 2) but the summary states that claims 12-16 are rejected. Appellant assumes that the detailed rejection applies to all claims under 35 USC §103(a) as being unpatentable over Kullas USP 6,436,072 in view of Dennehey et al. 4,201,406.

Kullas with a lubricant as taught by Dennehey so that the spike can be easily inserted into the irrigation bag" (page 2).

b. Kullas et al. 6,436,072.

Kullas discloses in Figure 1 a surgical irrigation system of the type generally described in this application. The pumping unit 1 is supported on an IV pole 18 from which two irrigation bags 8 are suspended. The inlet 10 for the pumping unit is coupled to the bags 8 by means of conventional spikes 14. The outlet 12 from the pump unit extends to a remote hand piece 16 which is manipulated by the surgeon to irrigate a surgical site.

c. Dennehey et al. 4,201,406.

Dennehey discloses a spike connector used to connect a tubing set to a container holding a sterile medical solution wherein maintenance of sterility is important. The example used is peritoneal dialysis in which a dialysate solution is introduced into a patient's peritoneal cavity and thereafter drained from the cavity to the original container or elsewhere. In such circumstances, the tubing may be used with a number of solution bags in which case the spike, if it is accidentally touched, will break sterility of the system, possibly resulting in peritonitis (column 1, lines 37-46).

In Dennehey, a medical solution bag is shown at 10 having ports 12 and 14. The spike connector 22 is preferably a one piece molded construction comprising a rear connector portion 24, a radially extending flange 26 and a spike 28. A tube 34 surrounds spike 28 and a spacer or bushing 36 is interposed between the spike and tube 34. The flange 26 extends radially from spike 28 a greater distance than the radial distance of tube 34 from spike 28.

The tube 34 protects the spike 28 from accidental touching while switching between the medical solution containers. The port 12 from the medical solution container is an elongated cylindrical member which fits over the spike 28 and abuts against the inside rear surface 38 of flange 26. When spike 28 ruptures a diaphragm 18 within port 12 the medical solution within the container 10 can flow through tubing 42 to the patient.

Dennehey states:

"Spikc 28 is preferably formed of a material having a relatively slippery surface so that the spike can be inserted easily into port 12. Lubricating material may be applied to the spike and may comprise silicone or other lubricating materials as are well known in the art." (column 3, lines 15-20)

d. The Present Invention Is Not Obvious.

It is simplistic to argue, as the Examiner has done, that since Kullas and Dennehey each disclose spike connectors and since Dennehey coats his spike connector with a lubricant, it is therefore *prima facie* obvious to coat Kullas' spike with a lubricant. This argument ignores a number of key factors:

First, Dennehey is not concerned with surgical irrigation in which an irrigant is coupled to a pumping unit and directed by a surgeon to a surgical site. Dennehey, instead, enables a patient to make multiple connections between a tubing set connected to the patient and a container holding a medical solution which is to be introduced into the patient.

Second, Dennehey is seeking to prevent the patient from contaminating the spike by touching. To achieve his objective, Dennehey surrounds the spike with a tubular protection member 34. As shown in Fig. 2, the port 12 fits tightly between the tube 34 and the spike 28. As a result, there is contact between both the inner and outer surfaces of port 12 and the tubular connection, i.e. the outer surface of spike 28 and the inner surface of tube 34 frictionally engage the inner and outer surfaces, respectively, of port 12. As a result, the frictional forces are substantially higher than would ordinarily be encountered if the spike alone were inserted into port 12. The reason for lubricating the spike 28 in order to ease its insertion into port 12 is not explained in Dennehey, but it is reasonable to assume that the need for lubrication arises because of the presence of the tube 34 and the additional frictional forces caused by the tube when the spike is inserted into the port.

Appellants' claims are directed to a surgical irrigator. Such irrigators have been known for many years yet prior to appellants' invention it was not suggested that the spike used to connect the irrigator to the irrigation bag should be lubricated. It is true that Dennehey teaches that a spike for a medical solution (not surgical irrigation, however) should be lubricated. But the reason for the

lubrication is not present in the case of a surgical irrigator. Appellants' surgical irrigator is discarded after a single use; there is no need to use it a second time. Consequently, there is no need to provide a protective tube or sleeve as taught by Dennehey to avoid contamination when the unit is subsequently used. Because there is no protective tube, a person of ordinary skill in the art would not consider it necessary to lubricate the spike used to connect the surgical irrigator to the irrigation bag. Consequently, despite the teaching of Dennehey, the prior art contains no suggestion or motivation to modify the references as proposed by the examiner.

One may concede that the application of a lubricant to overcome high frictional forces is not patentable. But that does not mean that it would be obvious to use a lubricant where friction is not a problem. The fact that Dennehey encounters a situation involving a medical device where a spike is subject to high frictional forces may suggest the need to lubricate the spike in that particular situation. It does not suggest that a spike which is not subjected to high frictional forces should be lubricated. Accordingly, the fact that Dennehey teaches the lubrication of a spike for his unique structure is not a general teaching that spikes in other situations should be lubricated. The prior art fails to disclose any reason or need to lubricate a spike in the case of a surgical irrigator; therefore, as a matter of law, the Examiner's proposed combination is improper and the rejection should be overruled.

IX. CONCLUSION

The present invention is not obvious over Kullas et al. in view of Dennehey et al. The reason for lubricating Dennehey's spike does not exist in Kullas. Accordingly, the Examiner's rejection under 35 U.S.C. §103(a) is improper and should be reversed with respect to all claims.

Dated: May 4, 2004

Respectfully submitted,

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APPENDIX A

Claims Involved in the Appeal of Application Serial No. 09/481,120

1.-11. (Cancelled)

12. (Previously Presented): A surgical irrigator, comprising a pumping unit having an inlet and an outlet, a handpiece and tubing connecting the outlet of said pumping unit to said handpiece, said pumping unit including a support for the pumping unit, a flexible tube connecting at one end to said inlet, and a spike connected to the other end of said flexible tube for connecting said inlet to an irrigation bag, said spike being adapted to penetrate a fitting in said irrigation bag and coated with a lubricant.

13. (original): A surgical irrigator according to claim 12, wherein said lubricant comprises silicone.

14. (Previously Presented): A surgical irrigator according to claim 12, wherein the spike is coated with lubricant in an amount that maintains sufficient friction between the spike and the fitting to support the weight of the spike and the flexible tubing.

15. (Previously Presented): A surgical irrigator according to claim 12, wherein the support comprises a pole.

16. (Previously Presented): A surgical irrigator according to claim 12, wherein the fitting comprises a membrane.